

REMARKS

Claims 1, 5, 6, and 20, as amended, and new claims 22-24 appear in this application for the Examiner's review and consideration. Claims 7-19 and 21 were withdrawn by the examiner as directed to non-elected subject matter. Claims 2-4 were cancelled. Applicants fully reserve their rights to prosecute the subject matter of any cancelled claim in one or more continuation, continuation-in-part, or divisional applications. Claims 1, 5, 6, and 20 have been amended to more particularly point out the claimed subject matter and to correct inadvertent minor spelling and editorial errors, but no new matter has been added. New claims 22 and 23 are support in the specification at p. 4, ll. 28-31, p. 8, ll. 17-21, and Example 4. New claim 24 is supported in the specification at p. 8, ll. 22-26.

Claim 20 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement for the reasons set forth on pages 4-7 of the Office Action. Applicants respectfully traverse.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See, e.g. Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). As long as a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, the written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996). “*Ipsis verbis* disclosure is not necessary to satisfy the written description requirement.” *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

The claim has been amended to recite that “the average AUC of said composition is at least 5% more than the average AUC of a non-menthol containing formulation.” Further, adequate support for the term “at least” is found in the specification as explained below. The Office alleges that claim 20 is not supported by the specification, however applicants believe the basis for this rejection is in error. Without explanation, the Office focuses its analysis on a section of the specification different than that pointed out by applicants in their reply to the Restriction Requirement mailed on March 13, 2008. Inexplicably, the Office focuses on the language of page 6, line 28 to page 7, line 11, stating that the application and claims fail to provide adequate written description for the term “at least.” Applicants request the Office to

focus on page 8, lines 17-21, where it is stated: “Typically, the amount of improvement should be at least about 5% of the average AUC as compared to the average AUC of a non-menthol containing formulation...” Hence, the expected improvement had been qualified by the phrase “at least” in sections of the specification, conveying that applicants clearly expected that such improvement meet this criteria. Hence, although *ipsis verbis* support is not required, the specification describes the terminology used in claim 20.

Thus, the rejection of claim 20 under 35 U.S.C. § 112, first paragraph, cannot stand and should be withdrawn.

Additionally, the terms “at least 10%” recited in new claim 22 and “at least 15%” recited in new claim 23 are also supported by the specification. While p. 4, ll. 28-31 and p. 8, ll. 17-21 of the specification discloses “about 10%” and “about 15%” in AUC improvement, respectively, Table 1 in Example 4 further disclose AUC improvements of over 10% and 15%. Specifically, Table 1 discloses an 81% improvement in AUC_t and a 102% improvement in AUC_I.

Claims 3, 6, and 20 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the reasons set forth on page 8 and 9 of the Office Action. Claims 6 and 20 have been amended and claim 3 has been cancelled rendering this rejection moot.

Thus, the rejections of claims 3, 6, and 20 under 35 U.S.C. § 112, second paragraph, cannot stand and should be withdrawn.

Claims 1-6 and 20 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by U.S. Patent No. 6,121,234 to Benet *et al.* (“the ‘234 patent”) in light of Ran *et al.*, “Solubilization of Cyclosporine A,” *AAPS PharmSciTech*, 2(1), 1-4 (2001) and “Herbal Medicines,” *Physicians Desk Reference*, 628-631 (2004) for the reasons set forth at pages 10-12 of the Office Action. Applicants respectfully traverse.

It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 231 USPQ 160 (Fed. Cir. 1986). Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868

F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Although the use of additional references to confirm the contents of an allegedly anticipating reference is permitted, anticipation does not permit an additional reference to supply a missing claim limitation.

Teleflex, Inc. v. Ficosa North American Corp., 299 F.3d 1313 (Fed. Cir. 2002).

The ‘234 patent fails to anticipate the claims because it lacks each and every element of the claims. The references fails to list the necessary drugs or the amount of menthol as recited in the claims. Given this lack of identity, the reference cannot anticipate the claims.

Further, the Office’s interpretation of the term “about 20%” to include 6% is so stretched that the Office does not propose any evidence in fact or law to support this interpretation. As noted above, the identical invention must be shown in as complete detail as is contained in the claim. And in this case, it is clear that 6% is not 20% or even about 20%. The number recited by the claim is over three times, *i.e.* 300%, the value cited by the Office as anticipatory. In fact, the Office’s interpretation is so strained that the Office has effectively read the term “20%” out of the claim.

Contrary to the Office’s argument, the term “about” is proper in a claim. For example, “a limitation defining the stretch rate of a plastic as ‘exceeding about 10% per second’ was definite because infringement could clearly be assessed through the use of a stopwatch.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983); M.P.E.P. 2173.05(b)(A). While the term is appropriate, it does not allow the Office to interpret the term for any numerical limitation, much less find grounds to argue an indefiniteness rejection within an anticipatory rejection as the Office has done here.

Consequently, the ‘234 patent does not anticipate the present claims. Accordingly, the rejection of claims 1-6 and 20 under 35 U.S.C. § 102(b) as anticipated cannot stand and should be withdrawn.

Claims 1-6 and 20 stand provisionally rejected under the doctrine of nonstatutory double patenting over claims 10 and 16-17 of U.S. Patent Application Serial No. 11/357,757, entitled “Drug Microparticles,” and published as 2006/14105235 (the ,235 publication”) for the reasons set forth at pages 12-115 of the Office Action. Applicants respectfully traverse.

The rejection can no longer stand in view of the amended claims.

Accordingly, it is believed that claims 1-6 and 20 are now in condition for allowance, early notice of which would be appreciated.

CONCLUSION

Applicants submit that the claims are allowable. An early and favorable action to that effect is respectfully requested.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 10-0600.

Respectfully submitted,
Kenyon & Kenyon LLP



Dated: March 11, 2009

By:

Michelle H.W. Shen
Registration No. 48,823

KENYON & KENYON LLP
One Broadway
New York, N.Y. 10004
Tel.: (202) 220-4200
Customer No: **26646**